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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,982	10/27/2005	Peter David Davis	3963.1000-000	1643

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EXAMINER	
BARKER, MICHAEL P	
ART UNIT	**PAPER NUMBER**
1626	

MAIL DATE	DELIVERY MODE
11/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,982	DAVIS ET AL.	
	Examiner	Art Unit	
	Michael P. Barker	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 Sept. 05, Preliminary Amendment*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29-31 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *27,29-31 and 33* is/are rejected.

7)☒ Claim(s) *29-31 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. *9/26/05;5/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant canceled **Claims 28, 32,** and **24,** amended **Claims 3-21, 23, 25-27, 29-31,** and **33** via a Prelminary Amendment filed 26 Sept. 2007. Accordingly, **Claims 1-27, 29-31,** and **33** are pending in this Application. **Claims 1-26** are drawn to allowable subject matter. **Claims 27, 29, 30, 31,** and **33** are rejected under 35 U.S.C. 112, ¶1 (scope of enablement).

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 26 September 2005 and 14 May 2007 were correctly filed. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS's were considered by the Examiner. Please refer to Applicant's copies of PTO-1449, submitted herewith.

Claim Rejections - 35 USC § 112 ¶1

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 29, 30, 31, and **33** are rejected under 35 U.S.C. § 112, first paragraph, because the Specification, while enabling for (1) ameliorating or reducing the incidence of certain proliferative disorders; (2) ameliorating or reducing the incidence of certain cancers; (3) ameliorating or reducing the incidence of certain hypoxic disorders; and (4) treatment of solid tumours or leukaemia, the Specification does not reasonably provide enablement for

(1) ameliorating or reducing the incidence of every proliferative disease; (2) ameliorating or reducing the incidence of every cancer; (3) ameliorating or reducing the incidence of every hypoxic disorder; or (4) prevention of solid tumours or leukaemia. Therefore, the Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'."

In re Wands, 8 USPQ2d 1400 (1988), discusses the following factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of skill in the art

The nature of the invention

Claim 27 is drawn to ameliorating or reducing the incidence of *every* proliferative disorder. **Claims 29**, **30**, and **31** narrow the scope of proliferative disorders to include *every* cancer, rheumatoid arthritis, psoriatic lesions, diabetic retinopathy, wet age-related macular degeneration, *every* hypoxic disorder, treatment of solid tumours and leukaemia, and *prevention* of solid tumours and leukaemia. **Claim 33** adds limitations on administration of the method described in **Claim 30**.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art, namely pharmacology, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instantly claimed invention is unpredictable in terms of the nonenabled subject matter of **Claims 27, 29, 30, 31,** and **33**.

As stated, pharmacology is an unpredictable art, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly complex, and one skilled in the art may recognize the claimed compounds as bioreductive and possibly antimitotic (either directly or peripherally within the mechanism of action) in assays. However, such properties do not mean that the same group of compounds and compositions may ameliorate or reduce the incidence of every type of proliferative disorder, ameliorate or reduce the incidence of every type of cancer or hypoxic disorder, or prevent solid tumours or leukaemia.

The state of the prior art, as evidenced in Applicant's Specification at pp. 1-3 supports Applicant's claims of using stilbene derivatives for the treatment of rheumatoid arthritis, psoriatic lesions, diabetic retinopathy, wet age-related macular degeneration, solid tumours, and leukaemia. However, even a recently published review of perhaps the most researched stilbene derivative to date, resveratrol, does not go so far as to claim stilbene derivatives are capable of

ameliorating or reducing the incidence of every type of proliferative disorder, ameliorating or reducing the incidence of every type of cancer or hypoxic disorder, or preventing solid tumours or leukaemia. Baur, et al. Therapeutic potential of resveratrol: the in vivo evidence. Nature Reviews: Drug Discovery. Vol. 5, June 2006, pp. 493-506.

The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance presented which substantiates Applicant's claimed compounds as capable of ameliorating or reducing the incidence of every type of proliferative disorder, ameliorating or reducing the incidence of every type of cancer or hypoxic disorder, or preventing solid tumours or leukaemia. The direction or guidance present in Applicants' Specification provides evidence that establishes the claimed compounds as cytotoxic, bioreductive, and capable of use in hypoxic environments, each *in vitro*. No *in vivo* data has been provided to support the scope of the instant claims.

The breadth of the claims, quantity of experimentation, and level of skill in the art

Claims 27, 29, 30, 31, and **33** encompass treating every proliferative disorder, every cancer, every hypoxic disorder, and preventing solid tumours and leukaemia. In order to *prevent* a disease, one would need to precisely identify those subjects likely to acquire such a disease, administer Applicant's claimed invention, and then demonstrate that if the identified subject did not develop the disease, such an effect was the direct result of administration of the claimed

invention. In order to treat a disease, one would need to demonstrate what the subject population is, what the necessary dose is for efficacy, and that the subject has recovered from such a disease.

Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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